DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2015

Terumo Cardiovascular Systems Corporation
Joshua P. Ewing
Senior Regulatory Affairs Associate
125 Blue Ball Road
Elkton, MD 21921

Re: K150542
Trade/Device Name: Terumo Pump Tubing
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: April 9, 2015
Received: April 10, 2015

Dear Mr. Ewing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
Indications for Use

510(k) Number (if known): K150542

Device Name: Terumo® Pump Tubing

Indications for Use:

The Terumo® Pump Tubing is intended to provide a conduit for extracorporeal fluid flow through a roller pump during cardiopulmonary bypass procedures. The tubing is intended for use in procedures lasting up to 6-hours in duration.

Prescription Use (Part 21 CFR 801 Subpart D)	**XX**	OR	Over-The-Counter Use (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Submitter Information:

Primary Contact:

This submission was prepared in March 2015 by**:**

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This submission was prepared for:

Terumo Cardiovascular Systems Corporation
28 Howe Street
Ashland, MA 01721
Registration #1212122

Device Names/Classifications:

Proprietary Name	Classification Name	Common Name
Terumo® Pump Tubing	Tubing, Pump, Cardiopulmonary Bypass (Code: DWE)	Pump Tubing, Cardiovascular Procedure Kits

Predicate Device(s):

The device submitted in this 510(k) maintains characteristics that are substantially equivalent to the following devices:

- 70D PVC Pump Tubing 3/32" x 1/16" (Pre-Amendment)

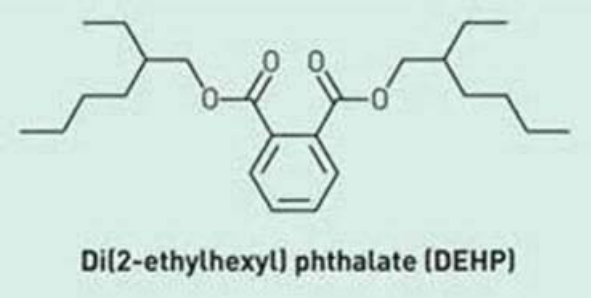
Indications for Use*:*

The Terumo® Pump Tubing is intended to provide a conduit for extracorporeal fluid flow through a roller pump during cardiopulmonary bypass procedures. The tubing is intended for use in procedures lasting up to 6-hours in duration.

Principles of Operation and Technology:
The 68D PVC Pump Tubing and the predicate device, 70D PVC Pump Tubing, use the same principles of operation and technology. The pump tubing that is the subject of this premarket notification may be used in a pump head and becomes cyclically compressed by the pump to cause the fluid to flow through the bypass circuit.

Design and Materials:
The Terumo® Pump Tubing is comprised of a commonly used polyvinyl chloride resin (PVC) that includes a plasticizer recognized as Di-(2-ethylhexyhl) phthalate (DEHP).

PVC is a plastic polymer that is used in a wide array of products. Unplasticized PVC is hard and brittle at room temperature. The plasticizer (softener) is typically added to increase the flexibility of the polymer. DEHP is the plasticizer for most PVC medical devices.



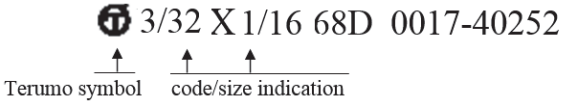
The PVC tubing that is the subject of this application is 68 durometer pump tubing (Shore A Hardness nominal measurement). It has a nominal inside diameter of 3/32" and a nominal wall thickness of 1/16". The outside diameter measures 7/32" (nominal).

The design differences between the 68D PVC Pump Tubing and the predicate device, 70D PVC Pump Tubing, include durometer, and print indicating manufacturer symbol, size, durometer, and part number:

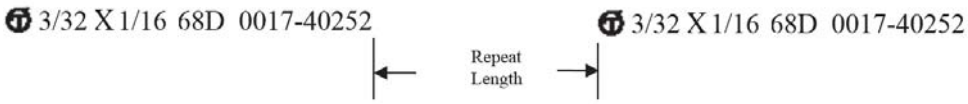
Device Characteristics	68D PVC Pump Tubing	Predicate: 70D PVC Pump Tubing
Durometer	68D (nominal)	70D (nominal)
Print on Outside of Tubing	Present	Not Present

The 68D PVC Pump Tubing will have a Shore A nominal durometer of 68D while the predicate device, the 70D PVC Pump Tubing, has a Shore A nominal durometer of 70D. The durometer dictates the hardness of the tubing.

There are no internal markings on the subject tubing. Outside markings consist of the Terumo symbol, followed by inner diameter (in inches) x wall thickness (in inches), durometer, and TCVS part number as shown below.



The texts of the notation are repeated every 5.75 to 6.25 inches as shown below.



Terumo Cardiovascular Systems Corporation concludes that the differences between the 68D PVC Pump Tubing and the predicate, 70D PVC Pump Tubing, do not affect the intended surgical use of the device nor do they affect safety and effectiveness of the device when used as intended.

Performance Evaluations:
Terumo Cardiovascular Systems Corporation conducted the following *in-vitro* performance evaluations to demonstrate the functional equivalence of the 68D PVC Pump Tubing to the predicate, 70D PVC Pump Tubing.

The following tests were performed, and summaries are presented on the ensuing pages:

- Visual Analysis
- Connection Strength
- Connection Leak Testing
- Roller Pump Performance (Durability)
- Dimensional Analysis
- Spallation
- Packaging Integrity Evaluation
- Shelf Life Evaluation

Substantial Equivalence Comparison:
In demonstrating substantial equivalence of the 68D PVC Pump Tubing to the predicate, 70D PVC Pump Tubing, a comparative study and/or assessment was performed in each of the following areas:

- Intended use
- Target Population
- Duration of use
- Product design
- Materials used in device construction
- Principles of Operation and Technology
- Product Specifications
- Product Performance
- Method of Sterilization
- Product labeling

Substantial Equivalence Statement:
The 68D PVC Pump Tubing is substantially equivalent in intended use, target population, duration of use, labeling, design, materials, principles of operation and technology, and performance to the predicate, 70D PVC Pump Tubing.

Additional Safety Information:

- Sterilization conditions for any packs containing 68D PVC Pump Tubing are validated to meet the requirements established in EN ISO 11135-1:2007. The validated processes ensure a minimum Sterility Assurance Level of 10-6. Product sterilization is controlled through strict maintenance of the processing parameters and, in some cases, post-sterilization biological indicator testing (if required for routine processing). Post-sterilization release for use is determined with consideration to maximum. Ethylene Oxide and Ethylene Chlorhydrin residue limits and maximum levels of exposure in accord with ANSI/AAMI/ISO 10993-7.

Conclusion:

Based upon the comparative studies and analyses, Terumo Cardiovascular Systems Corporation concludes that the 68D PVC Pump Tubing is *substantially equivalent* to the predicate, 70D PVC Pump Tubing. It is further concluded that any recognized differences noted during the assessments do not raise new issues of patient/user safety or product effectiveness.